

REMARKS

This Amendment is made in response to the Official Action mailed June 17, 2011. Claims 1-20 were previously cancelled. Claims 21 and 22 have been amended. Reconsideration and withdrawal of the objections to and rejections of the claims are respectfully requested in view of the above amendments, and further, in view of the following remarks.

Claim 21 has been amended in order to clarify that the invention relates to A dentifrice composition comprising a soluble calcium sequestering agent that is not an oxidizing agent, wherein the composition has an RDA value of below 30 and an IVSR value greater than 50, when compared to a Control dentifrice containing 14% Zeodent 113 abrasive silica in a conventional base containing water, sorbitol, glycerin, PEG, flavor, sodium lauryl sulphate, sodium saccharin, xanthan gum and sodium fluoride, and an orally acceptable vehicle, wherein the calcium sequestering agent is pentasodium tripolyphosphate present in a proportion of 1-20 wt % and an abrasive is present in a proportion of 0-2 wt % of the composition and wherein no silver ions are present in the composition. Claim 22 depends from claim 21 and is directed to a formulation that additionally contains a silica abrasive, wherein the silica abrasive has an RDA value below 30. Support for the amendments can be found in Example 10 and at page 6, lines 30-35 of the instant published specification.

Claims 21-22 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Action asserts that the parentheses in the claim make the claim unclear as to "whether the limitations are really the limitations or not". The parentheses have been removed from the claim. The "consisting of" language has been amended to "comprising" language and as such, addresses the confusion expressed in the Action. In view of the foregoing, reconsideration and withdrawal of the rejection are respectfully requested.

Preliminary to addressing the specific rejections made in the Action, Applicants present the following information on the record of this application. Applicants have prepared a dentifrice composition in accordance with Example 1 of WO 95/17158, cited in the ISR for this application. Both RDA and IVSR values were compared with that of a composition (Example 1) of the present invention. In order to provide IVSR values that are in accordance with the present invention, it was also necessary to prepare a "control" formulation as in the present invention. The following Table shows the various formulations that were tested.

Formulation 598: the 'Control' formulation of the present invention;
Formulation 599: Example 1 of the present invention;
Formulation 600: a formulation with 5% abrasive, that represents the lowest abrasive content formulation envisaged in documents cited herein;
Formulation 602: a formulation with 14% abrasive that represents a conventional formulation containing soluble calcium sequestering agents (water soluble alkali metal tripolyphosphate), closely matched to Example 1 of WO 95/17158.

| | Formulation 598 | Formulation 599 | Formulation 600 | Formulation 602 |
|-----------------------------|--------------------|--------------------|--------------------|--------------------|
| Ingredient | % w/w | % w/w | % w/w | % w/w |
| Glycerin, 98% min | 4 | 11.2 | 11.2 | 10 |
| Sorbitol, 70% soln. | 28 | 29.11 | 29.11 | 26 |
| Peg 6 | 3 | 3 | 3 | 3 |
| Xanthan gum | 0.8 | 0.7 | 0.7 | 0.7 |
| Carageenan Gum | 0.4 | 0 | 0 | 0 |
| Flavor | 1 | 1 | 1 | 1 |
| Soluble saccharin | 0.3 | 0.21 | 0.21 | 0.21 |
| Sodium lauryl sulphate | 1.5 | 1.15 | 1.15 | 1.15 |
| Sodium tripolyphosphate | 0 | 10 | 10 | 10 |
| Sodium fluoride | 0.31 | 0.24 | 0.24 | 0.24 |
| Titanium dioxide | 1 | 1.45 | 1.45 | 1.45 |
| Abrasive silica Zeodent 113 | 14 | 0 | 5 | 14 |
| Thickening silica | 9 | 13.5 | 11 | 6.5 |
| De-ionized water | 36.69 | 28.44 | 25.94 | 25.75 |
| Total | 100 | 100 | 100 | 100 |

The following table of results shows RDA values for the various formulations tested:

| Formulation No. | Product | RDA |
|-----------------|-----------------------------------|------|
| 598 | Control (14% Zeudent 113, no STP) | 77.6 |
| 599 | 0% Zeudent 113, 10% STP | 20.7 |
| 600 | 5% Zeudent 113, 10% STP | 49.3 |
| 602 | 14 % Zeudent 113, 10% STP | 98.0 |

The RDA value for Formulation 599 of 20.7 is clearly within the range anticipated by the present invention. The RDA value of all other formulations was well above the range disclosed and claimed in the present application.

The tooth stain removal performance of the formulations was assessed by the *In Vitro Stain Removal* (IVSR) method of Layer et al. The following table of results shows IVSR values (as % Control value) for the various formulations tested:

| Formulation No. | Product | % Control value |
|-----------------|-----------------------------------|-----------------|
| 598 | Control (14% Zeudent 113, no STP) | 100 |
| 599 | 0% Z113 silica, 10% STP | 80 |
| 600 | 5% Z113 silica, 10% STP | 105 |
| 602 | 14% Z113 silica, 10% STP | 144 |

The value of 80% of the Control IVSR value for Formulation 599 is clearly well within the limits specified in Claim 1 of the present application. As can be seen from the two tables of results, the RDA value of both 5% and 14% abrasive silica plus 10% STP was clearly outside the value claimed in the present invention. Not unexpectedly, adding abrasive to an STP formulation (Formulations 600 and 602) increases the cleaning performance, but not significantly until the 14% level is reached. What is surprising is that the results show that an abrasive is not actually needed for cleaning at a level broadly comparable with that of a conventional silica abrasive toothpaste formulation such as the Control.

Claims 21 and 22 have been rejected under 35 U.S.C. §102(b) and 35 U.S.C. §103(a), as being anticipated and/or made obvious by EPA 0002184. In particular, the Action asserts that EPA 0002184 "teaches use of sodium polyphosphate (read as chelating agent) in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify

action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation and the whole translation. The reference does not teach silica abrasive (emphasis added). Property of the dentifrice composition will be inherent to the composition since all required components are disclosed by prior art." In addition, the Action asserts that there is overlapping range of the chelating agent which establishes a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

Applicants urge that there are no formulation Examples in EPA 0002184, only two "application" Examples at the end of the document that show that the "polyphosphate fine granulate" is used in conjunction with a conventional toothpaste. EPA 0002184 very clearly discloses that the conventional toothpastes are "designed for average requirements" and therefore, one of skill in the art would have to assume that the abrasive levels are typical of an average toothpaste. This, to the skilled person, would mean that the abrasive levels in the formulation would on average be somewhere between 10-15%w/w. In order to support this view we can look, for example, at US4,996,042 (Wagner) (previously cited by the Examiner) in which there is a disclosure in column 2, line 35, that the proportion of polishing agents is between 20-60% by weight of the total composition. Therefore the compositions disclosed in EPA 0002184 will contain abrasive levels on the order of 10-15%w/w which would not give RDA values of less than 30, as required in the claimed invention.

Since EPA 0002184 does not teach each and every element of the claimed invention it cannot be said to anticipate the claims. Therefore, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 21 and 22 have been rejected under 35 U.S.C. §102(b) and 35 U.S.C. §103(a), as being anticipated and/or made obvious by JP Application No 01 237700 presented in IDS (also described as JP Publication No. 03099007). According to the Action, "JP teaches dentifrice composition comprising 0.1 % to 5.0% of calcium chelating/sequestering compound such as sodium tripolyphosphate, see abstract. The claimed property of RDA and IVSR will be inherent to the composition since the composition comprises the claimed chelating agent in the claimed range." In addition, the Action asserts that JP Application No. 01237700 teaches the overlapping range of the chelating agent sodium tripolyphosphates, and even such a slight overlap in range establishes a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 21 and 22 have been amended by including a proviso that the formulation does not contain any silver ions. This is distinct from JP Application No. 01237700 in that it discloses a "calcium ion-capturing substance and a silver compound". Applicants submit that this composition is meant to clean natural teeth and dentures, while having low abrasion properties. As such, it would be counterintuitive to one of skill in the art to include silver ions

in such a formulation. It is well known in the dentifrice art that silver compounds tend to stain most commonly causing intrinsic discoloration. For example, amalgam restorations can generate corrosion products (e.g., silver sulfide), leaving a gray-black color in the tooth. Therefore, one of skill in the art would not look to JP Application No. 01237700 when developing a formulation for gently cleaning teeth. Reconsideration and withdrawal of the rejections in view of JP Application No. 01237700 are requested.

Claims 11 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over EP A 0002184 in view of Kostinko et al. (US PG Pub 200310133882 A1). The Action admits that EPA 0002184 does not teach "pentasodium tripolyphosphate as calcium sequestering agent, chelating agent used in composition and abrasive silica". However, the Action then combines Kostinko because it "teaches abrasive composition for clear tooth paste, title. The reference teaches using pentasodium tripyrophosphate and sodium polymetaphosphate and tetra sodium pyrophosphate, see paragraph [0040]". "Abrasive silica is disclosed in examples, the dentifrice comprises abrasive silica in the range of 0.01 % wt to 35 wt % and RDA of greater than about 50 (emphasis added)". The Action asserts that it would have been obvious to one of ordinary skill to substitute pentasodium tripyrophosphate in the teachings of EP A 0002184 because substitution of one chelating agent with another would produce predictable results absent evidence of unexpected results. Reconsideration and withdrawal of the rejection are respectfully requested.

EPA 0002184 does not teach low abrasive toothpaste formulations, rather, it is clearly intended to cover conventional toothpaste formulations where the finely granulates polyphosphate is intended to intensify or to boost standard, conventional toothpaste formulations. These toothpaste formulations will contain, as discussed in the 2nd paragraph, traditional toothpaste abrasive materials such as calcium carbonate, dicalcium phosphate etc., which will be present in conventional abrasive levels and thus have RDA values above those claimed in amended claims 21 and 22. There is no motivation in EPA 0002184 to look at low RDA compositions.

Kostinko claims a dentifrice composition that has higher RDA values than those presently claimed, i.e., RDA values between 50 and 200, so the relevance to the present invention is not understood. One cannot correctly combine the EPA 0002184 STP formulation with Kostinko's high RDA reference and arrive at the present low RDA composition. The skilled person would not be looking at combining these two references to produce the instant invention. Therefore, a *prima facie* case of obviousness has not been established and reconsideration and withdrawal of the rejection are respectfully requested.

In view of the foregoing, favorable reconsideration of claims 21 and 22 and allowance of this application are earnestly solicited.

Respectfully submitted,

/Nora L. Stein/
Nora Stein
Attorney for Applicant
Registration No. 36,689

GLAXOSMITHKLINE
Corporate Intellectual Property UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-5044
Facsimile (610) 270-5090